K080605
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Curbell Electronics, Inc.

Special 510(k) Summary

MAY - 5 2008

1. Company: Curbell Electronics, Inc.
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Orchard Park, NY 14127
716-667-3377 x419
716-667-1390 fax

2. Contact: Michael J. Winter

2. Date Prepared: February 29, 2008

3. Trade Name: Sure-Lock electrode clip

4. Common Name: ECG electrode connector clip

5. Classification Name: Patient Transducer and Electrode Cable (including connector) (21CFR870.2900, Product Code DSA)

6. Predicate device: Current 510(k) (K884592), Astro Trace, model AT-01

7. Device description: ECG/EKG electrode clip

8. Intended use: Sure-Lock electrode clips provide a connection between lead wires and ECG/EKG electrodes (button & tab style).

9. Technological characteristics to predicate device: The proposed change to the Sure-Lock electrode clip does not affect the equivalence to the former legally marketed predicate device, Astro Trace, model AT-01, (K8844592).

The differences in the proposed changes to the Sure-Lock electrode clip to the predicate device are the following:

- Change the insulator material from polymethylpentene to polycarbonate (Makrolon). Reference Engineering Test Report: SURE-LOCK Material Comparison-Polymethylpentene and Makrolon 2458, Section 11.
- Change the DFU/label to require a "3mm-4mm safety banana plug" instead of a "3mm-4mm banana plug." Reference attached DFU/label, Section 12.

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- Change the DFU/label to add a Caution: "Cleaning with alternate compounds and methods may damage product. Contact Curbell for cleaning assistance." Reference Engineering Test Report: SURE-LOCK Connector Performance, Section 11. Reference attached DFU/label, Section 12.
- Change the DFU/label to add a Note: "Sure-Lock Electrode Clip may be subjected to 10 sterilization cycles by ethylene oxide method." Reference Engineering Test Report: ECG Cables and Leads Verification Testing, Section 11. Reference attached DFU/label, Section 12.
- Change the DFU/label to include: "The following electrodes (reference electrode table in DFU/Label) have been tested and are suitable for use with Sure-Lock electrodes. Contact Curbell for application assistance." Reference Engineering Test Report: SURE-LOCK Electrode Compatibility, Section 11. Reference attached DFU/label, Section 12.

10. Nonclinical performance data:

The proposed changes to the Sure-Lock electrode clip have been assessed to the following performance standards:

- ANSI/AAMI EC53:1995 and EC53/A1:1998.

11. Clinical data: None

12. Conclusion from nonclinical testing: There are no questions or differences in the safety and effectiveness of the proposed changes to the Curbell Sure-Lock electrode clip to the predicate device.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY - 5 2008

Curbell Electronics, Inc.
c/o Mr. Michael J. Winter, RAC
Director, Quality and Regulatory Affairs
20 Center Dr.
Orchard Park, NY 14127

Re: K080605
Sure-Lock Electrode Clip, Model CL-34, CL-A60, CL-HW, CL-TL
Regulation Number: 21 CFR 870.2900
Regulation Name: Patient Transducer and Electrode Cable (including connector)
Regulatory Class: Class II (two)
Product Code: DSA
Dated: April 8, 2008
Received: April 14, 2008

Dear Mr. Winter:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K080605

Indications for Use

510(k) Number (if known): K080605

Device Name: Sure-Lock Electrode Clip

Indications For Use: Sure-Lock electrode clips provide a connection between lead wires and ECG/EKG electrodes (button & tab style).

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Donna R. Michaels
(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K080605